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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,394	09/10/2003	Patrick Mailliet	03806.0491-01	2263
5487 7590 04/02/2007 ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER JARRELL, NOBLE E	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/02/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/02/2007.

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Office Action Summary	Application No. 10/658,394	Applicant(s) MAILLIET ET AL.	
	Examiner Noble Jarrell	Art Unit 1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>3/14/2007</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/26/2003 and 9/10/2003</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION***Status of Application***

1. The Response to Election / Restriction dated February 27, 2007 is acknowledged with traverse. Group I is elected with claims 22-24 and 27-33. Group I is defined as the following: in the general formula of claim 22, both the nitrogen-containing aromatic ring and aromatic ring are defined as quinoline, and the distribution agent is defined as pyrimidine. After completing the search, claims 25-26 were rejoined with claims 22-24 and 27-33 because the search burden was not as great as initially thought. After the telephonic interview, the elected species is bis-2,4-[(4'-amino-6'-quinaldiny)amino]-pyrimidine-trihydrochloride pentahydrate.

Applicants contend that groups I-IV share a common utility and common structure, since both the nitrogen-containing aromatic ring and the aromatic ring of the general formula of claim 22 are both defined as quinoline in each restriction group. However, these groups do not share a common structure due to the different group present as the distribution agent. The distribution agent is the following in each group: group I, pyrimidine; group II, a carbonyl group; group III, a C(=NH)-NH-C(=NH) group; and group IV, a alkylidyl group containing 3 to 7 carbon atoms. These four groups are not equivalent to each other, and therefore, groups I-IV cannot share a common structure. Applicants also contend that there is no serious burden to search all the possibilities of the structure. Groups I-IV do represent a serious burden on the examiner to search each and every possibility of each group. If the examiner were to search each possibility for the nitrogen-containing aromatic ring, a separate structural query for each of the three possibilities, based on that part alone. If the distribution agent is defined as a diazine, three possibilities exist for the diazine: pyrimidine, pyrazine, or pyridazine. When the other three possibilities are added in for the distribution agent, there are a total of six possibilities. Each of the diazine is separate from one another in terms of structure. In the analysis of the aromatic ring, there are at least 5 possibilities for the ring. If this ring is benzamidine, the same structural query cannot be used if the ring is phenyl. The last possibility, a mono-, bi-, or triheterocyclic ring system can be many ring systems. There is no indication whether the ring system is aromatic, saturated, or alicyclic, and based on the broadest reasonable interpretation, the ring can be any heterocyclic ring system composed of up to three rings with at least 1 heteroatom. A serious burden does exist for the examiner to search all groups I-IV together, as well as groups V-XIII, since they are each related to groups I-IV. The restriction is deemed proper and MADE FINAL.

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Information Disclosure Statement

2. The information disclosure statement filed September 10, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because none of the documents were submitted. Therefore, the documents were not considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

3. The disclosure is objected to because of the following informalities: The reference for the synthesis of example 15 does not exist.

Appropriate correction is required.

Allowable Subject Matter

4. Claims 22-24 and 27-33 contain allowable subject matter, that being working example 15 of the specification. Although this compound was only found in applicants' work (WO2001040218, published June 7, 2001), but not found in any prior art on the record. The closest prior art is WO2001020418, and that is why this compound is found to be allowable.

Applicants should amend the claims to eliminate non-elected subject matter to put the application under allowable condition. As the claims currently stand, the general formula of claim 22, *nitrogen-containing aromatic ring-NR₃-distribution agent-NR₃-aromatic ring*, encompasses many different structures. The *nitrogen-containing aromatic ring* has minimally 3 possibilities, a minimum of 6 possibilities for the *aromatic ring*, a minimum of 4 possibilities for the *distribution agent*, and 8 possibilities each for *NR₃* and *NR₃'*. The current scope of the claim is much broader than the elected group and species, and therefore must be amended to reflect the election of group I.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the core where the nitrogen-containing aromatic ring and the aromatic ring are both quinoline and the distribution agent is a diazine (pyrimidine, pyrazine, or pyridazine), does not reasonably provide enablement for compounds not covered by the definitions of these groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants are enabled for the synthesis and use of working example 15. Example 15 is shown to have anti-telomerase and cytotoxic activity. Since this core structure is novel in terms of the variables nitrogen-containing aromatic ring, aromatic ring, and diazine, compounds with this core are enabled for the inhibition of telomerase.

Applicants are not enabled for the use of the group and the species to treat all forms of cancer, as cited in claim 26.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. The factors are: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quality of experimentation needed to make or use the invention based on the content of the disclosure.

Breadth of the claims: applicants are not enabled for compounds that are not encompassed by the elected group and species are not enabled. Examples of these compounds include (but are not limited to) example 5 on page 40 of the specification. The only compounds that are enabled are those compounds that have quinoline in the positions of variables *nitrogen-containing aromatic ring* and *aromatic ring*, and the *distribution agent* is a diazine (pyrimidine, pyrazine or pyridazine). Only one working example is shown in the specifications, working example 15. This is the only compound mentioned in the entire specification that falls within the elected group and species.

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Quality of experimentation needed to make or use the invention based on the content of the disclosure: Claim 26 cites the use of the elected compounds to treat any form of cancer. However, each different type of cancer is composed of one or more cell lines. Brattain et al. (Cancer Metastasis Reviews, 1984, 3(3), 177-191)(based on the abstract) report the establishment of a large bank of cell lines for colon cancer. Brattain et al. developed these cell lines from primary human colon carcinomas and grouped them based on tumorigenicity in athymic mice, their growth rates in soft agarose and in tissue culture, and their secreted levels of carcinoembryonic antigen. Applicants have to show testing for each and every different cell line for cancer to be enabled for this method of use.

Applicants are not enabled for compounds not encompassed by the elected group and species, as well as the method of treating cancer, as explained by the above rationale.

Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on Monday-Friday from 7:30 to 5:00. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (571) 272-0572. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NU


VICKIE KIM
PRIMARY EXAMINER